

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------------|----------------------|---------------------|------------------|
| 09/890,649 | 10/26/2001 | Michael W. Dahm | 24741-1529 | 5173 |
| 26633 | 7590 02/10/2005 | | EXAMINER | |
| | EHRMAN WHITE & I | CANELLA, KAREN A | | |
| 1666 K STREET,NW SUITE 300 WASHINGTON, DC 20006 | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|--|---|--|--|--|--|
| Office Action Summan | 09/890,649 | DAHM ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Karen A Canella | 1642 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 6(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _• | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | · · · · · · · · · · · · · · · · · · · | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under E. | x <i>parte Quayle</i> , 1935 C.D. 11, 45 | 3 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>36-48 and 51-87</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) <u>36-38,51-55,77-79 and 81-87</u> is/are rejected. | | | | | | |
| 7) Claim(s) <u>39-48,56-76 and 80</u> is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner | · | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the d | lrawing(s) be held in abeyance. See | 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correcti | | • • | | | | |
| 11) ☐ The oath or declaration is objected to by the Exa | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a) | -(d) or (f). | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received | | | | | | |
| 1. Certified copies of the priority documents have been received.2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau | • | a in the Hational Stage | | | | |
| * See the attached detailed Office action for a list of | | d. | | | | |
| | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary (Paper No(s)/Mail Da | | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/13/2004. | | atent Application (PTO-152) | | | | |
| | | | | | | |

Page 2

DETAILED ACTION

- 1. Claims 49 and 50 have been canceled. Claims 36-48, 51-76, 86 and 87 have been amended. Claims 36-48 and 51-87 are pending and under consideration.
- 2. Sections of the text of Title 35, U.S. Code, not found in this action can be found in a previous action.
- 3. Claim 87 remains rejected under 102(e) as being anticipated by Ts'o et al (US 5,962, 237) for the reasons of record set forth in the previous Office action. Claim 87 is a product by process claim. Ts'o disclose the culture of tumor cell lines obtained by the disclosed methods. The tumor cells isolated by the method of Ts'o would have the same characteristics as the corresponding tumor cells isolated by the instant methods.
- 4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. In reBerg, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998): In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993): In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1642

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Page 3

- 5. Claims 36-38, 51-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 28, 29, 30, 31, 48 and 49 of U.S. Patent No. 6, 821, 726. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '726 anticipate the instant claims.
- 6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 77-79 and 81-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayres (US 3, 945, 928, reference A3 of the IDS filed Apr 13, 2004).

Ayres disclose a tubular container closed at both ends; elastomeric barrier means fixedly located intermediate the container ends attached to the inner side wall of the container and dividing the container into first and second chambers such that upon separation of the blood into the light phase and the heavy phase by the application of centrifugal force, the first chamber contains only the light phase; a passageway through the barrier means connecting the first and second chambers, said barrier means further including a conical surface, adjacent the first chamber, which forms a funnel that is in communication with the passageway to facilitate the separation of the phases and the flow of the heavy phase into the second chamber; a valve seat defined by a wall of the barrier means disposed about the passageway; and a flexible flap valve means extending over the valve seat having one portion of the edge fixed to the barrier means and the other portions of the edge free, the flap means having a specific gravity greater than blood and normally sealing off the passageway to provide a barrier between first and second chambers, and when subjected to a predetermined centrifugal force, the flap means flexes away from the valve seat to open the passageway to provide communication between the chambers to

Application/Control Number: 09/890,649

Art Unit: 1642

permit the major portion of the light phase to travel to the first chamber and the heavy solid phase to travel to the second chamber; and upon cessation of the applied centrifugal force, the flap means returns to its normal position on the valve seat to seal off the passageway and provide a barrier between the first and second chambers (claim 1) that fulfills the specific embodiments of claims 77-79 and 83-86. Regarding claims 81 and 82, it is reasonable to conclude that the thickness of the flap would fall between 1-5 mm given the scale of the drawing provided.

Page 4

- 8. Claims 39-48, 56-76 and 80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 9. All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicants amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Page 5

2/7/2005

1. Genella LAPH.D